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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/509,348

Applicant(s)

SHALEV, ILAN

Examiner

BHISMA MEHTA

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 16-18, 25, 36-38, 40-43, 48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 19-24, 26-35, 39, 44-47, and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Amended claim 50 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 50 is drawn to an apparatus having extensions which do not provide a channel of fluid communication through which a fluid sample can be conducted to outside of the body channel. Claim 50 is therefore drawn to a nonelected species as the elected species (shown in Figures 2A, 2B, 2C, and 2D) has extensions which do provide a channel of fluid communication through which a fluid sample can be conducted to outside of the body channel (line 28 of page 11 to line 20 of page 12).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 50 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Objections

2. Claims 5-10 are objected to because of the following informalities: In claims 5-10, the use of "a said impediment" is objected to as parts of the body cannot be claimed. It is suggested that the phrase "a said impediment" in these claims be replaced with "the impediment" as it is clear from Applicant's remarks on pages 15 and 16 filed January 10 2008 that the impediment referred to in claims 5-10 is the impediment referred to in claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-15, 19-24, 26-30, 32-35, 39, and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry (U.S. Patent No. 5,857,998). Barry discloses an apparatus having a hollow tube (30) defining at least one aperture (40, 42, 47, 52 – lines 59-66 of column 7, 233 – lines 45-55 of column 10) configured for the intake of fluid and located on the hollow tube and at least one extension (35, 36) operative to be at at least two positions with respect to the at least one aperture. In the first position, the extension is near at least one aperture. In the second position, at least part of the extension extends away from at least one aperture. If the at least one aperture is blocked by an impediment, the relative movement of the at least one extension with respect to the at least one aperture is considered to be capable of dislodging the impediment from the at least one aperture. As to claim 2, the at least one aperture comprises a front inlet at a front end of the hollow tube. As to claim 3, the at least one aperture comprises one or more side openings in a side of the hollow tube. As to claim 4, the at least one aperture comprises at least one front opening at a front end of the hollow tube and at least one side opening in a side of the hollow tube. As to claims 5-10, in the Figures, Barry shows an impediment in the form of an aggregate of solid material, a venous valve, or an inflamed body tissue and which is located down

flow from the hollow tube or at least partly within the hollow tube. The apparatus is structured such that moving the at least one extension from the first position to the second position would allow for the displacement of an impediment which is located down flow from the hollow tube or at least partly within the hollow tube. As to claims 11 and 12, Barry teaches that the apparatus may be left in a the patient's body between treatments (lines 21-26, column 9) and disclose the claimed structural elements of the device, thus, the device of Barry is capable of being implanted in a patient's vein for a period of one or more weeks and/or months. As to claims 13-15, 19, and 20, the apparatus includes an activating mechanism which causes the at least one extension to extend from the first position to the second position or to un-extend from the second position to the first position where the activating mechanism is configured for manual activation due to the manual operation of the apparatus and for automatic activation as a result of the delivery of inflation fluid. As to claims 21-24, Barry discloses the claimed structural elements of the apparatus, thus, the apparatus of Barry is capable of being adapted such that delivery of the fluid may be performed before, after, or during the movement of the at least one extension or such that at least some of the movement of the at least one extension takes place irrespective of the delivery of the fluid through the at least one aperture. As to claims 26 and 27, the at least one aperture (40) is covered or arranged to be covered by the at least one extension in the first position. As to claims 28-30, the apparatus comprises a material that is capable of preventing or retarding aggregation of solid from a bodily fluid or clot formation or body tissue inflammatory response (lines 10-28 of column 8). As to claims 32-35, the at least one

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extension (35, 36) comprises at least one expandable element which expands when filled with expansion fluid, the apparatus includes an activating mechanism with a reservoir containing expansion fluid which is used to expand the extension, and the expansion fluid comprises a material that affects the formation of impediments and the at least one expandable element is at least partly impermeable to the material (lines 29-50 of column 8 and lines 9-30 of column 9). As to claim 39, the at least one extension comprises resilient extensions. As to claims 44 and 45, Barry teaches that the apparatus may be adapted for veins, arteries, and other locations in a patient's body and discloses the claimed structural elements of the device, thus, the apparatus of Barry is capable of being adapted for an arm vein and for a non-vein vessel (lines 34-44 of column 6). As to claims 46 and 47, the at least two positions are axially displaced and radially displaced.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry in view of Zadno-Azizi (U.S. Patent No. 6,958,059). Barry discloses the apparatus substantially as claimed. However, Barry is silent on the specifics of the apparatus comprising a material that prevents or retards bacteria colonization. Zadno-Azizi

discloses an apparatus for treating an impediment which comprises a material which is capable of preventing or retarding bacteria colonization (see line 44 of column 13 to line 6 of column 14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the apparatus of Barry with a material to prevent or retard bacteria colonization as both Barry and Zadno-Azizi disclose apparatus for treating impediments and Zadno-Azizi teaches that it is well known to provide the apparatus with a material such as an antibiotic to prevent or retard bacteria colonization as bacteria colonization can lead to complications for the patient undergoing the medical procedure.

7. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barry. Barry discloses the apparatus substantially as claimed. Even though Barry disclose the apparatus may be used in any of the diverse passageways in a patient's body (lines 34-44 of column 6) and, thus, the dimensions (such as length and diameter) of the hollow tube will be selected according to the intended use of the apparatus, Barry is silent on the specifics of the hollow tube having a length of not more than 10 cm. The instant disclosure describes the parameter of length as being merely preferable, and does not describe it contributing any unexpected results to the tube. As such, the parameter of length is deemed a matter of design choice (lacking in any criticality), well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results. Applicant should note that in line 28 of page 13 to line 2 of page 14 of Applicant's specification, the length of the hollow tube is disclosed as being less than 10 cm or as being greater than 10 cm (i.e., as calculated when the length of the portion of

the hollow tube within the body is added to the length of the portion of the hollow tube that is outside of the body).

Response to Arguments

8. Applicant's arguments with respect to claims 1-15, 19-24, 26-35, 39, 44-47, and 49 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Simons/
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